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October 1, 1992

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-[ ]

On behalf of the Regulatee and pursuant to Units II B.1.b; II C and II D of the [ ] CAP Agreement, [ ] hereby submits (in triplicate) the attached information. Submission of the information in this letter is made voluntarily under a recently published TSCA §8(e) reporting Q/A, June 1991 TSCA 8(e) Reporting Guide ("Reporting Guide") and is not to be construed as a waiver of due process rights, or as an admission of TSCA violation or that Regulatee's activities with the study compound(s) reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which was not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide" states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation. the informal issuance of the "Reporting Guide" raises significant due process issues and

RECEIVED 9/22/95

clouds the appropriate reporting standard by which regulated persons can assure TSCA §8(e) compliance.

Regulatee is claiming certain bracketed "[ ]" information in this submission as Confidential Business Information and has provided substantiation and a redacted copy for the public file.

For Regulatee,

[

]

"PUBLIC COPY"

CAP Confidentiality Claim: Submitter ID (including internal codes a personnel), Mixture Composition, Mixture ID, Use.

1. Confidential treatment should be afforded for an initial period of ten years. At that time the submitter will review business needs and, if warranted, may request reasonable extensions to that time period. Technology represented by the mixture is not easily protecte from competitors by obtaining patents, therefore, the submitter has maintained these compositions as trade secrets.

A ten year period is requested because the current lifetime of most [ ] is generally ten years. However, the technology base of [ ] may exceed ten years. In such cases extensions may be requested.

2. No.

3. No. Not to our knowledge. The submitter's practice is to disclose composition identity to outside parties only under terms of a security agreement or to the government with claims of confidentiality or trade secrecy.

4. All documents which reveal proprietary chemicals which comprise the mixture composition are stored in locked, limited access facilities. These documents are identified as being proprietary, secret, or confidential. As a condition of employment, employees are contractually prohibited from disclosing confidential information outside the company.

5(a) No.

(b) No.

(c) No.

(d) No.

6. [ ] quality is critical to product performance and directly impacts market share. An estimated 10-20 million dollars is required to improve manufacturing processes in order to produce [ ] with improved [ ] manufacture. The entire value of this improvement can be eliminated by the choice [ ]

Additionally [ ] are now evaluated based on environmental impact, [ ] uniformity and performance characteristics, and safety. All of these qualities must be "engineered in" to our [ ] at some substantial investment. An estimated minimum value of commercializing a [ ] can exceed $50,000.

Disclosure of [ ] composition would impact the submitter's competitive position per the following:

- If a competitor sees several formulas containing similar materials he could be reasonably sure that these materials are c on-going interest to the submitter, and therefore have competitive value.
- Disclosure of the mixture composition (chemical identity of the components) would disclose the specific [ ] formula or would make it easy for a competitor to produce the same or a similar mixture with significantly less R & D investment since the choice of mixture components would be disclosed.
- A competitor could determine a time sequence in testing based on the dates of the disclosed studies, and determine what research direction the submitter is following. For example it would be possible to track progression from one major component [ ] to another. Although the use of [ ] is generally known, competitors do not know which of these materials is considered "better" and worthy of pursuing commercially.
- Knowing that toxicity testing is not cheap, a competitor can readily assume that any composition tested by the submitter has some commercial / competitive value.
- Although the toxicity test does not identify which [ ] the [ ] is applied to, a general knowledge of [ ] requirements in the marketplace would make it easy to determine the [ ] based on the [ ] components.

7. Submitter does not agree that chemical identity is "health and safety data". Without waiving this objection submitter answers the following:

   (a) No.

   (b) Yes. This information could be established based on a precise listing of the components.

   (c) Yes. Chemical identity information, internal codes, and personnel could disclose submitter identity and would enable our competitors to benefit from our investment in new technology.

Submitter Identity

Because the submitter is recognized for its [ ] technology, competitors could search submissions selectively for [ ] and, with limited investment and testing required, try them on their own products.

-- Submitter's participation in the CAP is now a matter of publ record.

2. The tested mixtures are generally similar in that they are composed of [

]

3. It is likely that a competitor skilled in the art of [ ] production or [ ] will recognize or guess that, even with generic descriptions of components, the mixtures end use is that of a [ ].

4. Disclosure of submitter ID with generic composition ID will make it much easier for a competitor to know that the tested material is, in fact, a [ ] as submitter is recognized as a leader in [ ] production.

Composition

Revealing specific [ ] would open the door for our competitors to precisely reproduce formulations which have been developed at significant expense. Our competitors may well be able to establish a composition as [ ] solely on the basis of the nature of its ingredients even without making an association with the submitter or the use.

Use

Competitors could quickly scan submissions for this application, and use this information to develop a database re. trends in [ ] technology without incurring R&D and testing costs which have been borne by the submitter.

Chem/ CAS # See below
Generic Chem: A trialkylol alkane alkyl triester with nonionic PEG ester and Peg ether emulsifiers, an anionic fatty soap, a polyalkylene glycol and a phosphite
Title:
Inhalation Approximate Lethal Concentration
Date: 6/22/82
Summary of Effects: ALC = 2.6 mg/l.

Material Tested

Study Initiated/Completed
2/12/82-3/3/82

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC)

Summary: Groups of 6 male Crl:CD® rats were exposed nose-only for single 4-hour periods to aerosol atmospheres containing . AN ALC was found to be 2.6 mg/L which is considered moderately toxic.

Procedure: Male albino Crl:CD® rats were housed in pairs in 8" x 8" x 14" stainless steel wire mesh cages. Purina Certified Rodent Chow® #5002 and water were available ad libitum. Rats were weighed and observed for general suitability for at least 1 week prior to test.

Groups of 6 rats, 7-8 weeks old and weighing 233-258 grams, were placed in perforated stainless steel restrainers and exposed nose-only to single 4-hour periods to aerosol atmospheres containing . Several exposures were conducted at different concentrations until an ALC was determined. Surviving rats were weighed and observed daily for 14 days post exposure (weekends excluded except when deemed necessary).

Generation: The liquid test material was heated (25-30 C) in a reservoir and metered with an FMI pump through a Spraying Systems® nebulizer. Preheated (50-65°C) dilution air, added at the nebulizer, aerosolized the test material and swept it into the test chamber.

Analytical: Chamber atmospheric concentrations were determined by gravimetric analysis. Calibrated volumes of chamber air were drawn through preweighed Gelman glass fiber filters at 2.0 L/min. Samples were taken at 30-minute intervals. Concentrations were determined from filter weight gain (mg) per liter of chamber air sampled. Filters were weighed on a Cahn 26 Automatic Electrobalance®.

Results: During exposure, a fine mist was visible to the unaided eye. Exposure data follow:

Concentration (mg/L)			Fractional Mortality
Mean	S.D.	Range	#Deaths/# Exposed
0.57	0.11	0.44-0.76	0/6
2.6	0.80	1.9-4.1	1/6 (1 day post exposure)
7.3	0.85	5.6-8.4	6/6 (1 during exposure, 2 @ 1 day, 3 @ 2 days).

Clinical Observations:

During exposure - Observations could not be made because rats were exposed nose-only.

Post exposure - In a dose-dependent manner, all rats exhibited moderate to severe weight loss 24-48 hours post exposure, after which surviving rats resumed a normal rate of weight gain. Lung noise was observed at 0.57 mg/L for 2 days, at 2.6 mg/L for 14 days and at 7.3 mg/L until death. Wet perineum was observed for 2-3 days in rats at all levels. Compound-stained fur and red nasal discharge were observed for 2 to 3 days at 2.6 and 7.3 mg/L. At 7.3 mg/L, salivation, gasping, hyperactivity, and tremors were observed until death.

An Approximate Lethal Concentration for is 2.6 mg/L. Based on Haskell Laboratory Acute Toxicity Classifications, this material is moderately toxic via inhalation exposure.

Purity: 95%

Contaminants: Water

Synonym: None

CAS Registry No.: None

Work and Report by:

Supervised by:

Study Director:

Approved by:

Date Issued: June 22, 1982

Material Tested

Study Initiated/Completed
1/8/82 - 1/28/82

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC)

Summary:

Male rats were exposed to atmospheres containing for single, 4-hour periods. An Approximate Lethal Concentration on a dry weight basis is 0.53 mg/L which is considered highly toxic. The calculated ALC for (with approximately 82% water) is 2.9 mg/L which is moderately toxic.

Procedure:

Male albino Crl:CD® rats were housed in pairs in 8" x 8" x 14" stainless steel wire mesh cages. Purina® Certified Rodent Chow #5002 and water were available *ad libitum*. Rats were weighed and observed for general suitability for at least 1 week prior to test.

Groups of 6 rats, 7-8 weeks old and weighing [illegible] grams, were exposed to atmospheres of the test material for single, 4-hour periods. Exposures were conducted at several concentrations until an ALC was determined. All surviving rats were weighed and observed daily for 14 days post-exposure, weekends excluded except when deemed necessary.

Generation:

Atmospheres of were generated by syringe driving the finish through a Spraying Systems® nebulizer. The resultant aerosol was sprayed onto the heated (212-230°C) surface of an Instatherm® flask. Dilution air carried the test material from the mixing flask to the chamber.

Analytical:

Chamber atmospheres were analyzed gravimetrically at 30-minute intervals by passing calibrated volumes of test atmosphere through preweighed glass fiber filters. Atmospheric concentrations were determined from dry weight gain of the filters.

Results:

A slight yellow discoloration was seen in the flask and delivery tube; no visible cloud was noted in the chamber although there was condensation on the chamber walls. Results were as follows:

Concentration (mg/L)				Fractional Mortality
Mean	Mean (Dry Weight Basis)	S.D.	Range	#Deaths/#Exposed
0.39	0.07	0.03	0.02-0.11	0/6
1.1	0.19	0.07	0.14-0.24	0/6
2.9	0.33	0.26	0.21-0.79	5/6

Observations:

During Exposure: Rats exposed to 0.07 mg/L exhibited no adverse clinical signs. At higher concentrations, rats exhibited rapid and labored breathing, hyperemia, piloerection and red nasal discharge. At 0.33 mg/L 1 rat also exhibited a hopping gait.

Post-Exposure: At concentrations ≤ 0.19 mg/L, rats showed slight to no weight loss at 24 hours followed by weight gain. At .33 mg/L all rats except 1 showed severe weight loss, labored breathing, hyperemia, and dry red ocular discharge. Deaths occurred within 48 hours. The survivor rat showed slight weight loss for 48 hours followed by weight gain.

An Approximate Lethal Concentration for on a dry weight basis is 0.33 mg/L which is considered highly toxic. The calculated ALC for (with approximately 32% water) is 2.9 mg/L which is moderately toxic.

Work and Report by:

Supervised by:

Study Director:

Aprroved by:

Date Issued: May 26, 1982

Triage of 8(e) Submissions

Date sent to triage: 12/14/95

NON-CAP CAP

Submission number: 12380A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

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entire document: (0) 1 2 **pages** 1, 1st tab **pages** 1, all tabs

Notes:

Contractor reviewer : UPS **Date:** 4/11/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 -12380 (S) SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: Confidential

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/01/92 OTS DATE: 10/14/92 CSRAD DATE: 02/22/95

CHEMICAL NAME: CAS#

A trialkylol alkane alkyl triester with Confident
nonionic PEG ester and PEG ether emulsifiers,
an anionic fatty soap, a polyalkylene glycol and
a phosphate

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL. TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
(0209)	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
(0224)	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
(0243)	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RAT	(LOW)		
CAS SR	NO	NO (CONTINUE)		MED		
	(IN TRAMINI)	REJ-T-R		HIGH		

COMMENTS

12380A

L

Acute inhalation toxicity in rats is of low concern. In one study, single 4-hour inhalation exposures to male Crl:CD rats (6/group) at levels of 570, 2600, and 7300 mg/m^3 were lethal (0/6, 1/6, and 6/6, respectively). Clinical signs included salivation, gasping, hyperactivity, and tremors at the high concentration and lung noise at all concentrations. In another study, single 4-hour inhalation exposures to male Crl:CD rats (6/group) at levels of 390, 1100, and 2900 mg/m^3 were lethal (0/6, 0/6, and 5/6, respectively). Clinical signs included rapid and labored breathing, hyperemia, piloerection, and abnormal gait in high-concentration animals.